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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,468

12/31/2003

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,468	Applicant(s) MOLINA ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,9-14,17-25,27 and 29-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,9-14,17-25,27 and 29-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the Request for Continued Examination based on the 10/749468 application filed December 31, 2003. Claims 1-3, 5, 6, 9-14, 17-25, 27, and 29-49 as amended are currently pending and considered below.

Response to Amendment

1. In response to applicant's amendments to the claims, the previous claim objections and rejections under 35 U.S.C. 112 have been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 32, 1, 5, 8, 10, 11, 6, 9, 33-37, 43-48; 38, 21-25, 27, 29-31, 39-42, 49; 2, and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/064909 A1 to Donohue et al.

Regarding claims 32, 1, 5, 10, 11, 6, 9, 33-37, 43-48; 2, and 3 Donohue et al disclose a tubing (1) for conveying fluidic media comprising at least one layer of COPE (Paragraph [0016]) where the at least one layer of COPE comprises an outer surface defining an outer peripheral surface of the tubing and an inner surface. Further, Donohue et al disclose an inner layer having an open internal passage (3) and an intermediate layer for bonding the outer layer to the inner layer (2), wherein the intermediate layer comprises EVA (Paragraph [0020]) and the inner layer is comprised of polyurethane (Paragraph [0019]), wherein the outer and intermediate layers are free of PVC (Paragraph [0008]). COPE itself is a barrier to carbon dioxide, thus Donohue et al also disclose that the outer layer (of COPE) is a barrier to carbon dioxide. Further, the tubing comprises no more than one layer of COPE material (1), consists essentially of no more than one layer of COPE material (1), is free from other layers other than the at least one layer of COPE (1), the at least one layer of COPE is substantially free of

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other materials (1), and the inner surface is coated with a material for enhancing fluidic compatibility with the media (COPE). Donohue et al also disclose a second layer for bonding (2) between an inner layer (3) and a third layer comprised of COPE (1).

Regarding claims 38, 21-25, 27, 29-31, 39, and 49, Donohue et al disclose a process of making a tubing comprising selecting a COPE material and forming a tube (Paragraph [0021]) having at least one layer of COPE (1), wherein the COPE material comprises an outer peripheral surface and an inner peripheral surface of the tubing (see above). Further, Donohue et al disclose forming no more than one layer of the COPE (1), forming an inner layer (3), and forming an intermediate layer (2). Donohue et al further disclose that the outer layer is extruded COPE (1), the intermediate layer is extruded EVA (2), and that the layers can be singularly or co-extruded (Paragraph [0021]) and that the tubing is free from PVC (Paragraph [0008]) and the outer layer is a barrier to carbon dioxide (1).

However, Donohue et al do not explicitly teach that the innermost surface is comprised of COPE. At the time of the invention, one having ordinary skill in the art of medical tubing would have recognized that COPE is a useful material in making medical grade tubing without the use of harmful plasticizers (Paragraph [0016]) and would therefore find it obvious to make any or all layers of a medical tubing out of COPE. Donohue et al further disclose that the intermediate layer is comprised of EVA (2). Donohue et al also fail to explicitly teach or disclose the use of a plurality of layers of COPE material or that EVA is used between each set of adjacent layers of COPE. However, the examiner notes that the use of multiple layers of COPE tubing interspaced

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with EVA is simply a duplication of parts already disclosed by Donohue et al (layers 1 and 2) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 40-42, Donohue et al disclose all the limitations of claim 38 as disclosed above, but fail to teach or disclose the extrusion of a plurality of layers of COPE material or that EVA is extruded between each set of adjacent layers of COPE. However, the examiner notes that the extrusion of multiple layers of COPE tubing interspaced with EVA is simply a duplication of parts within a process already disclosed by Donohue et al (layers 1 and 2; Paragraph [0021]) and therefore would have been an obvious matter of design choice to one having ordinary skill in the art, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

6. Claims 12-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donohue et al in view of USPN 6,248,093 B1 to Moberg.

Regarding the above claims, Donohue et al disclose the device of claim 6 as described above, but fail to teach or disclose its use in a system. Moberg teaches a drug delivery system (Fig. 1) combining a pump (101, 102, 103, 104), reservoir (105), and tubing (106) for the delivery of insulin (Col. 1, lines 14-16). Further, Donohue et al disclose that the material of the second layer of tubing is EVA (2), that each of the second and third layers is comprised of a single layer (Fig. 1), that the intermediate and

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outer layers are free of PVC (Paragraph [0008]) and that the outer layer is a barrier to carbon dioxide (1). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to use the tubing of Donohue et al in the medical system of Moberg because the tubing of Donohue et al does not contain plasticizers, which Donohue notes in Paragraph [0003] is detrimental to the delivery of insulin, such as that being delivered by the device of Moberg. Therefore, it would have been obvious to combine Donohue et al with Moberg to obtain the invention in the instant claims.

Response to Arguments

7. Applicant's arguments filed October 7, 2009 have been fully considered but they are not persuasive.

8. Regarding applicant's statement that it would not be obvious to modify Donohue et al such that the innermost surface is comprised of COPE, the examiner disagrees. The examiner first notes that the phrase, "any and all" was a typographical error in the previous action and should have read, "any or all". The current action has been corrected to read as such. Regardless, however, the examiner notes that, while the inner layers of Donohue et al have been described as providing flexibility, good fluid flow, and compatibility, the examiner notes that Donohue et al never state that the outer layer of COPE does not also have these properties. Simply mentioning the useful characteristics of the inner layers is not tantamount to requiring their presence to perform a particular function, and thus the examiner maintains it would have been obvious to one having ordinary skill in the art to investigate different combinations of

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materials provided in the tubing of Donohue et al, including but not limited to a single layer of COPE, or an additional layer of COPE on the interior of the tubing.

9. Regarding applicant's argument that the advantages of the prior art are evidence of it's non-obviousness, the examiner notes that simplification of manufacturing and improved manufacturing tolerance are motivations that drive innovation, but do not provide sufficient evidence as to the non-obviousness of applicant's invention over the prior art. In fact, these advantages are expected results from such a modification and therefore, in contrast, support the obviousness of the modification of Donohue et al. Expected beneficial results are evidence of obviousness just as unexpected results are evidence of nonobviousness. In re Skoner, 517 F.2d 947, 186 USPQ 80 (CCPA 1975).

10. Applicant's arguments toward the combination of Donohue et al and Moberg are directed only at the purported insufficiencies of Donohue et al previously addressed above.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

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/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763